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| 09/576,097 | 05/22/2000 | Laman Alani | 6499.US.O2 | 3170 |

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EXAMINER

LUKTON, DAVID

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 01/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/576,097

Applicant(s)

ALANI ET AL.

Examiner

David Lukton

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2006.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-11 and 14-21 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1,3-11 and 14-21 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/11/06 has been entered.



Pursuant to the directives of the response filed 1/11/06, claims 1, 7-9, 14-21 have been amended. Claims 1, 3-11, 14-21 remain pending.

The claim listing filed 1/11/06 is not correct. The listing shows claims 12 and 13 as pending. However, these claims were cancelled pursuant to the directives of the response filed 5/21/02. Claims 1, 3-11, 14-21 are thus pending.

Applicants' arguments filed 1/11/06 have been considered and found persuasive in part. The 112, 2nd paragraph rejection is withdrawn.



Claim 16 is objected to because of a spelling error. In line 1 of the claim, the term "compositon" is misspelled.



The following is a quotation of 35 USC. §103 which forms the basis for all obviousness rejections set forth in the Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art

are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 1, 3-11, 14-21 are rejected under 35 U.S.C. §103 as being unpatentable over Sham (WO 97/21685) in view of Yamamoto (USP 5,264,223) or Yamamoto (USP 5,756,123).

As indicated previously, Sham discloses (beginning on page 126, last paragraph) the invention substantially as claimed, except for the presence of water. Yamamoto ('223) discloses capsules in which the water content is about 5%; Yamamoto ('123) discloses capsules in which the water content is in the range of 1-6%. Yamamoto does not disclose the claimed compositions. The claims encompass the possibility of a completely anhydrous composition being contained within a capsule that contains a small quantity of water such that the overall composition, including the capsule, contains 0.4% to 3.5% water.

In response to the foregoing, applicants have argued that Yamamoto teaches that decreasing the water content to a point below 10% is desirable. Applicants have not identified the passage where this might be stated, but even if such a statement is present, the fact remains that Yamamoto discloses the desirability of having a water content which is as

high as 8%. Applicants have argued that Yamamoto does not teach “the addition of water to increase the solubility”. However, Yamamoto does most certainly teach the addition of water, but the addition of water is to the materials used to produce the gelatin capsules. It may be that Yamamoto does not teach “the addition of water” to the formulation that is contained within the capsule, but that was never the basis of the rejection anyway. The basis of the rejection is that there is nothing in the language of claim 1 to preclude the possibility that the “composition” in question is such as to include a gelatin capsule. Were it the case that the claims were drawn to a method of increasing solubility of drugs, then applicants arguments might be appropriate. But this is not what the claimed invention is.

The rejection is maintained.



Claims 1, 3-11, 14-21 are rejected under 35 U.S.C. §103 as being unpatentable over Al Razzak (USP 5,948,436).

As indicated previously, Al Razzak teaches the elements of the claimed invention. Applicants have argued that the compositions of Al Razzak do not contain fatty acids. It may be true that the disclosed compositions do not contain free fatty acids, but they contain fatty acids nonetheless, as indicated in col 6, line 50+.

In response to the foregoing, applicants have argued that a lipid chemist or an organic chemist encountering the phrase “solvent which comprises a fatty acid”, without further qualification, would have no doubt that esters of fatty acids are affirmatively excluded.

However, as indicated in the previous Office action, the issue is primarily one of semantic laxity. As indicated previously, one example of this is the term “amino acid”, which more often than not really refers to an amino acid residue. There is another example which one can point to. As applicants may be aware, there is some concern among cardiologists with regard to foods which contain *trans* fatty acids. The food industry has responded by offering foods which are asserted to contain low levels of *trans* fatty acids. In reality, however, what is meant by this is not so much that the *trans* fatty acids *per se* are absent, but rather that esters of *trans* fatty acids are absent. Nor is it the case that this “semantic laxity” is confined to newspapers and magazines that are consumed by the lay public. Such blurring of the lines between *trans* fatty acids per se and *trans* fatty acid esters also permeates the scientific literature and the patent literature.

Adding to the ambiguity (fatty acids *versus* fatty acid esters) is a claim such as claim 8 which asserts that if one has 40 parts fatty acid and 3 parts ethanol, one is in possession of an organic solvent. Note that lauric acid, for example, has a melting point of 44-46 °C and hardly qualifies as a solvent. However, a mono- or didodecanoyl ester of glycerol, together with a small quantity of ethanol would come much closer to being a solvent than the embodiment which applicants are arguing is a solvent.

Applicants are assuming a level of semantic rigor which is not in evidence. If it were really the case that applicants believed that the term “fatty acid” invariably means *free fatty acid*, applicants would feel no reluctance in amending the claims to recite the latter term. As matters currently stand, however, the rejection is maintained.



THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED AND ANY EXTENSION FEE PURSUANT TO 37 CFR 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached at (571)272-0974. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



**DAVID LUKTON
PATENT EXAMINER
GROUP 1800**